UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|---|---|---|---|
| 10/775,972 | 02/10/2004 | Robert A. Henderson | 210121.455C21 | 1812 |

500 7590 04/21/2006

SEED INTELLECTUAL PROPERTY LAW GROUP PLLC
701 FIFTH AVE
SUITE 6300
SEATTLE, WA 98104-7092

| EXAMINER | |
|---|---|
| YAO, LEI | |

| ART UNIT | PAPER NUMBER |
|---|---|
| 1642 | |

DATE MAILED: 04/21/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/775,972 | HENDERSON ET AL. | |
| | Examiner | Art Unit | |
| | Lei Yao, Ph.D. | 1642 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *21 February 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *8 and 12-16* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *8 and 12-16* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

## *DETAILED ACTION*

The Amendment filed on 2/21/06 in response to the previous Non-Final Office Action (11/18/05) is acknowledged and has been entered.

Claims 1-7 and 9-11 have been cancelled. Claim 8 has been amended. Claims 12-16 have been added. Claims 8 and 12-16 are pending and under consideration.

**The text of those sections of Title 35, U.S.Code not included in this action can be found in the prior Office Action.**

**The following office action contains NEW GROUNDS of rejection.**

### *Rejections*

The rejections of Claim 8 are withdrawn in view of amendment to the claims.

Because of giving a new date for priority and addition of new claims in this amendment new grounds of rejections and maintained rejection **will be stated below.**

### *Response to Argument*

***Priority-new priority given***

The objection of applicant's claims to an earlier effective filing date through US non-provisional application, 09285479 filed 4/2/1999 is withdrawn, however the new priority for the claims will be given as 11/30/2001 and reason is discussed as follows:

First, Applicant argue that the Application 09/221107 ('107) filed 12/22/1998 disclosed protein having SEQ ID NO: 161 and on page 25, describes the used of antibodies as therapeutic agents. In response to this argument, the claims recite a method for stimulating an immune response in a patient, comprising administering to the patient an isolated antibody or antigen-binding fragment thereof, which specific binds to polypeptide of SEQ IDNO: 161, disclosure of protein (SEQ ID NO: 161 and antibodies as a therapeutic agent do not encompass a specific method for stimulating an immune response by injection of antibody to a patient.

Second, upon review of specifications of the provisional applications, it is noted that the prior issued patents or applications filed before 12/17/1999 do not provide adequate support of administering a patient an antibody and that prior issued patents or applications filed before 11/30/2001 do not provide support for stimulating immune response by administering a patient an antibody or antigen-binding fragment. Therefore, for the purposes of examining this application, the examiner has established the effective priority dated according to Application 10/007700 filed **11/30/2001** as the filing dated of the instant claims that recite a method for stimulating an immune response in a patient comprising administering to the patient a composition comprising an antibody or antigen-binding fragment to a polypeptide of SEQ ID NO: 161. If applicant disagree with any rejection set forth in this office action base on this priority date, applicant is invited to submit evidence pointing to the serial number, page and line where support can be found establishing an earlier priority date.

***The following is a New Ground of rejection***

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

1. Claims 8 and 12 are rejected under 35 U.S.C. 102(b) as being anticipated by Holroyd et al., (WO 99/44620, publication date, 9/10/1999) as evidenced by Abbas et al., (page 393, column 2, section antibodies, Cellular and Molecular Immunology, 4th edition, Published by W.B. Saunders Company, 2000).

Holroyd et al., disclose antibody to an ICACC family protein comprising ICACC-1 and ICACC-2. The protein ICACC-2 is 99.6% identical to the protein of SEQ ID NO: 161 in the instant claims as evidenced by protein sequence search (see Exhibit A as attached in prior office action). Holroyd et al., disclose that ICACC family proteins are highly conserved in the amino acid sequences by protein alignment (figure 5A). Holroyd et al., also disclose a pharmaceutical composition comprising antibodies to ICACC-1 and a method of administering the antibodies to a subject to treat a disease in an individual (page 26, para 3, page 27, pare 2, page 29, para 2). It is inherent that administration of any foreign substance including a polypeptide antibody will stimulate an immune response (as evidenced by Abbas et al., page 393, column 2, section).

2. Claims 8 and 12 are rejected under 35 U.S.C. 102(e) as being anticipated by Holroyd et al., (US Patent No, 6576434, effective filing date, 3/3/1999) as evidenced by Abbas et al., (page 393, column 2, section antibodies, Cellular and Molecular Immunology, 4$^{th}$ edition, Published by W.B. Saunders Company, 2000).

Holroyd et al., disclose antibody to an ICACC family protein comprising ICACC-1 and ICACC-2. The protein ICACC-2 is 99.6% identical to the protein of SEQ ID NO: 161 in the instant claims as evidenced by protein sequence search (see Exhibit A as attached in prior office action). Holroyd et al., disclose that ICACC family proteins are highly conserved in the amino acid sequences by protein alignment (figure 5A). Holroyd et al., also disclose a pharmaceutical composition comprising antibodies to ICACC-1 and a method of administering the antibodies to a subject to treat a disease in an individual (col 17, line 56-60, col 19, line 36-40, line 60-67 and col 20, line 1-5). It is inherent that administration of any foreign substance including a polypeptide antibody will stimulate an immune response (as evidenced by Abbas et al., page 393, column 2, section).

3. Claims 8 and 12 are rejected under 35 U.S.C. 102(e) as being anticipated by Pauli et al., (US Patent, 6309857, effective filing date, 11/17/1997) as evidenced by Abbas et al., (page 393, column 2,

section antibodies, Cellular and Molecular Immunology, 4th edition, Published by W.B. Saunders Company, 2000).

Pauli et al., disclose a protein, hCLCA2 shown as SEQ ID NO: 3, which is specifically expressed in lung and 99.7% identical to the protein having amino acid sequence of SEQ ID NO: 161 as evidenced by protein sequence search (see Exhibit B attached in prior office action). Pauli et al., disclose that hCLCA2 shares a high degrees of identity (86%) with lung-endothelial cell adhesion molecules (Lu-ECAM-1, col 10, line 38-44). Pauli et al., further disclose pharmaceutical composition comprising an antibody to protein Lu-ECAM-1 and a method of administering to a patient a therapeutically effective amount of the composition comprising the antibody to prevent lung-metastatic tumor spreading in an individual (col 21-22, example 9). It is inherent that administration of any foreign substance including a polypeptide antibody will stimulate an immune response (as evidenced by Abbas et al., page 393, column 2, section).

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 8 and 12-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over by Holroyd et al., (WO 99/44620, publication date, 9/10/1999) or Pauli et al., (US Patent, effective filing date, 11/17/97) in view of Abbas et al., (page 393, column 2, section antibodies, Cellular and Molecular Immunology, 4th edition, Published by W.B. Saunders Company, 2000) and Brown et al., (US Patent, 5459043, 10/17/1995).

The antibodies and administering the antibody to a patient as a therapeutic agent taught by Holroyd et al., and Pauli et al., are set forth above.

Holroyd et al., or Pauli et al., do not explicitly teach the method of stimulating an immune response using the antibody coupled to a therapeutic agent comprising radionuclide, toxin, or a drug.

Abbas et al., teach that antibodies to eliminate tumor cells has been demonstrated, which include killing tumor cells by activating complement or by antibody-dependent cell-mediated cytotoxicity, (a series of immune response, Abbas et al., page 393, column 2).

Brown et al., teach an antibody, which recognizes an antigen epitope associated with human cancer. Brown et al., teach that the antibody can be coupled with other therapeutic agents to form a conjugate, such as antibody-drug, antibody-toxin, or radiolabeled antibody for the purpose of therapeutically use (column 2, paragraph 3).

It would have been prima facie obvious to one of ordinary skill in the art at the time the claimed invention was made to use the method to stimulate an immune response by administering the antibodies and antigen-binding fragments to a protein (SEQ IDNO: 161) to a patient. One of ordinary skill in the art would have been motivated with a reasonable expectation of success to combine the teachings of Abbas et al., and Brown et al., to the teachings of Holroyd et al., or Pauli et al., to use the method for stimulating an immune response by administering a patient the antibody, antigen binding fragments, antibody conjugate to radionuclide, toxin, or drug, which could all bind to a polypeptide of SEQ ID NO: 161 because Holroyd et al., or Pauli et al., have shown antibodies, which could bind to a protein having high percentage or amino acid identity to the polypeptide of SEQ ID NO: 161 and a method of administering a patient an antibody for immunotherapy for a cancer, Abbas et al., have shown that eliminating tumor by

antibody is involved in a series of immune response and Brown et al., have shown that antibody is coupled to a radioactive agent, a toxin or a drug.

**Conclusion**

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lei Yao, Ph.D. whose telephone number is 571-272-3112. The examiner can normally be reached on 8am-4.30pm Monday to Friday.

Any inquiry of a general nature, matching or file papers or relating to the status of this application or proceeding should be directed to Kim Downing for Art Unit 1642 whose telephone number is 571-272-0521

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew can be reached on 571-272-0787. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Lei Yao, Ph.D.
Examiner
Art Unit 1642

LY

SHEELA HUFF
PRIMARY EXAMINER